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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/607,179

06/29/2000

Yuan Chang

45185-CA/JPW/SHS

1263

7590

08/09/2006

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EXAMINER

SCHLAPKOHL, WALTER

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/607,179	Applicant(s) CHANG ET AL.	
	Examiner Walter Schlapkohl	Art Unit 1636	<i>waf</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 May 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 52 and 53 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 52-53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the papers filed 5/25/2006 in which claim 52 was amended. Claims 52-53 are pending and under examination in the instant Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 52-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record set forth in the Office action mailed 2/22/2006.**

Response to Arguments

Applicant argues that those skilled in the art would recognize that the subject application discloses a deposited cell line, HBL-6, infected with Kaposi's sarcoma associated herpesvirus (KSHV). Applicant further argues that those skilled

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in the art would recognize that the subject application disclosed the full nucleic acid sequence identified as SEQ ID NO: 14, which is the open reading frame, designated ORF21, of the thymidine kinase (TK) gene of the disclosed KSHV. Applicant further argues that those skilled in the art would further recognize that the subject application indicates that the amino terminus of the KSHV TK gene is not conserved in other herpesvirus TK sequences. "Thus," Applicant argues, "those skilled in the art would recognize applicants to be in possession of a unique KSHV sequence that is not conserved among herpesviruses genomes" and "[t]hose skilled in the art would recognize that portions of this unique sequence can be used to express polypeptides that bind to antibodies which would be specific for the KSHV" (see first full paragraph of page 5 of Applicant's remarks submitted 5/25/2006).

Applicant's arguments have been carefully considered but have been respectfully found unpersuasive. Applicant's contention that possession of a full-length genomic sequence, as well as a unique KSHV sequence not conserved in other herpesvirus TK sequences, is enough to lead those skilled in the art to recognize portions of the unique sequence which can be used to express polypeptides that bind to antibodies which would be specific for the KSHV is unsupported. Which sequences are in

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fact specific for the KSHV? Any arguments which address genomic sequences or a novel thymidine kinase sequence are irrelevant because Applicant has not claimed such sequences as the invention. Instead, Applicant has claimed those sequences of the TK gene which Applicant's remarks identify as "specific for the KSHV" without describing them in such a way as to make clear to one of ordinary skill in the art which polypeptide sequences are specific for the disclosed KSHV and not for some other protein or virus.

Claims 52-53 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **Applicant's amendment to the claims is found remedial and the new matter rejection is hereby withdrawn.**

Claims 52-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This rejection is maintained for reasons of record as set forth in the Office action mailed 2/22/2006.**

Response to Arguments

Applicant argues that one skilled in the art can practice the claimed method without undue experimentation. Applicant further argues that under MPEP §2164.01, the fact that experimentation may be complex does not necessarily make it undue if the art typically engages in such experimentation. Applicant further argues that those skilled in the art can isolate the sequence identified as SEQ ID NO: 14 from the deposited cell line and can confirm that the correct sequence has been isolated by comparing it to the sequence disclosed in the subject application. Applicant further argues that those skilled in the art can routinely isolate nucleotides of various lengths from SEQ ID NO: 14 and incorporate these sequences into various expression vectors. Applicant further argues that the respective polypeptides can be expressed, isolated and used to produce specifically-binding antibodies.

Applicant's arguments have been carefully considered and have been respectfully found unpersuasive. Examiner agrees with

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Applicant insofar as MPEP §2164.01 makes clear that complex experimentation is not necessarily the same as undue experimentation with regard to enablement. Examiner also agrees with Applicant insofar as methods of DNA isolation, polypeptide expression and antibody production are routine for one of ordinary skill in the art. However, Applicant's contention that the use of fragments of SEQ ID NO: 14 to produce peptides/polypeptides which can then be used to generate antibodies which are determinative of a herpesvirus associated with Kaposi's sarcoma, which herpesvirus is present in and recoverable from the HBL-6 cell line was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For example, which peptide subsequences encoded by which 30 nucleotide portion of SEQ ID NO: 14 could be used such that the antibody binding reaction is determinative of a Kaposi's sarcoma associated herpesvirus and not some other protein or some other virus? Even in one were to consider one of the most narrow embodiments encompassed by Applicant's claims, wherein one of ordinary skill in the art were to use a peptide from the region of the TK gene not conserved in other herpesvirus TK sequences, Applicant's assertion that such a peptide could be used to generate a

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specifically-binding antibody is unsupported and not described in the specification or the prior art. In other words, Applicant has not demonstrated that even portions of the TK gene which are not conserved in other herpesvirus TK sequences are necessarily determinative of the KSHV present in the HBL-6 cell line.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view

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the scanned images of their own application file folder(s) as well as general patent information available to the public.

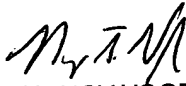
For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

July 26, 2006


NANCY VOGEL
PRIMARY EXAMINER